RESEARCH PAPER

Assessment of the Efficacy of Zinc Acetate as an Adjunct to Topical Triamcinolone Acetonide in Patients with Oral Lichen Planus: A Randomized Clinical Trial

Running Title: *Zinc Acetate as Adjunct in Oral Lichen Planus*

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Abstract

Background

Oral lichen planus (OLP) is a chronic inflammatory disease with an immune mediated etiopathogenesis involving the oral mucosa. Topical corticosteroids are considered as the first-line of treatment; however, recurrence is common and may not get completely resolved. Zinc has antioxidant, anti-inflammatory, and immunomodulatory properties that may improve therapeutic outcomes when administered as an adjunct to corticosteroid therapy.

Aim

To evaluate the efficacy of oral zinc acetate as an adjunct to topical triamcinolone acetonide in reducing burning sensation and lesion severity among patients with oral lichen planus.

Materials and Methods

A randomized clinical trial was conducted among 40 patients diagnosed clinically as having oral lichen planus according to established clinical criteria. Participants were allocated into two equal groups using computer based randomization. Group A received topical 0.1% triamcinolone acetonide in Orabase twice daily, whereas Group B received oral zinc acetate (15 mg) in addition to topical 0.1% triamcinolone acetonide. Burning sensation was evaluated using the Visual Analogue Scale (VAS), and lesion severity was assessed using the Thongprasom scoring system at baseline, day 7, day 14, and day 30. Statistical analysis was performed using SPSS version 20, with $p < 0.05$ considered as statistically significant.

Results

A total of 40 patients with oral lichen planus were included and randomly allocated into two groups (n=20 each). Both groups showed a significant reduction in burning sensation scores from baseline to the 30-day follow-up (p=0.001). The mean VAS score decreased from 7.60 ± 2.010 to 0.75 ± 0.639 in the triamcinolone acetonide group and from 8.70 ± 1.949 to 0.65 ± 0.813 in the zinc acetate adjunctive group. However, intergroup comparison of VAS scores showed no statistically significant difference at any follow-up visit ($p > 0.05$). Clinical evaluation using the Thongprasom scale demonstrated significant improvement in lesion severity in both groups (p=0.000), with complete lesion resolution observed in 75% of patients in Group A and 80% of patients in Group B at the 30-day follow-up.

Conclusion

Adjunctive oral zinc acetate may enhance the clinical response to topical triamcinolone acetonide in patients with oral lichen

planus. Zinc supplementation appears to be a safe and promising adjunctive therapeutic option; however, larger randomized controlled trials with longer follow-up are necessary to confirm its long-term efficacy.

Keywords: Oral lichen planus; Zinc acetate; Triamcinolone acetonide; Corticosteroids; Randomized controlled trial

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Introduction

Oral lichen planus (OLP) is a is a chronic inflammatory disease with an immune mediated etiopathogenesis involving the oral mucosal epithelium. It is characterized by $CD8^+$ T-cell-mediated apoptosis of basal keratinocytes, leading to basement membrane disruption and chronic inflammation of the oral mucosa. [1,2] OLP affects approximately 0.5–2.6% of the adult population and demonstrates a slight female predominance. [3] Clinically, it presents as reticular, papular, plaque-like, atrophic, erosive, and bullous forms, with the erosive and atrophic variants

presenting with pain, burning sensation, and impaired quality of life. [4,5]

Although the exact etiopathogenesis remains incompletely understood, considerable evidence suggests that OLP is primarily a T-cell-mediated autoimmune disorder. Activated cytotoxic T lymphocytes release inflammatory cytokines, including tumor necrosis factor-alpha (TNF-α), resulting in basal cell degeneration and persistent inflammation. Oxidative stress further contributes to epithelial injury through excessive production of reactive oxygen species, thereby aggravating disease progression. [2,18]

Oral lichen planus is recognized by the World Health Organization as an oral potentially malignant disorder (OPMD), with an overall malignant transformation rate of approximately **1%**, necessitating long-term clinical follow-up. [9] Diagnosis is based on a combination of characteristic clinical findings and histopathological features, while direct immunofluorescence may be useful in atypical cases to exclude other immune-mediated vesiculobullous disorders. [19–22]

Topical corticosteroids remain the first-line treatment for symptomatic OLP because of their potent anti-inflammatory and immunosuppressive properties. Among these, 0.1% triamcinolone acetonide is widely prescribed owing to its effectiveness in reducing pain and promoting lesion healing. [23,42] However, recurrence following treatment discontinuation, incomplete lesion resolution, and adverse effects associated with prolonged corticosteroid therapy remain significant therapeutic concerns. [23,40,41]

Zinc is an essential trace element that functions as a cofactor for more than 300 enzymes involved in cellular proliferation, epithelial regeneration, antioxidant defence, immune regulation, and wound healing. [26,35] Several studies have demonstrated reduced serum zinc levels in patients with OLP, particularly in erosive disease, suggesting that zinc deficiency may contribute to disease severity through impaired immune function and increased oxidative stress. [2,27,28,34] Furthermore, zinc supplementation has been shown to reduce inflammatory activity, promote epithelial repair, and improve clinical symptoms in patients with OLP. [31–33]

Recent randomized clinical trials have reported that oral zinc administered as an adjunct to topical corticosteroid therapy results in greater reductions in pain intensity, lesion severity, and inflammatory biomarkers compared with corticosteroid therapy alone. [9,44] Nevertheless, evidence regarding the efficacy of zinc acetate as an adjunctive therapy remains limited, particularly in the Indian population.

Therefore, the present randomized clinical trial was undertaken to evaluate the efficacy of oral zinc acetate as an adjunct to topical 0.1% triamcinolone acetonide in patients with oral lichen planus by assessing changes in burning sensation using the Visual Analogue Scale (VAS) and lesion severity using the Thongprasom scoring system.

Materials and Methods

Study design

This randomized clinical trial was conducted in the Department of Oral Medicine and Radiology, Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India. The study was designed to evaluate the efficacy of oral zinc acetate as an adjunct to topical triamcinolone acetonide in the management of oral lichen planus (OLP). Ethical approval was obtained from the Institutional Ethics Committee before commencement of the study, and written informed consent was obtained from all participants prior to enrolment.

Study population

A total of **40 patients** from the outpatient section of the Department of Oral Medicine and Radiology who had been clinically diagnosed as having oral lichen planus were given details of the proposed study, and informed consent was obtained followed by their recruitment into the study group. Eligible participants were randomly allocated into two equal groups using computer based randomization (n = 20 each). **Group A (Control group)** received Topical 0.1% triamcinolone acetonide in Orabase applied twice daily, while **Group B (Study group)** received Oral zinc acetate 15 mg once daily along with topical 0.1% triamcinolone acetonide in Orabase applied twice daily. Both treatment protocols were continued for two months, and patients received routine oral hygiene instructions and dietary advice. Clinical outcomes were evaluated at baseline, day 7, day 14, and day 30. Inclusion criteria considered before allocation were patients with age above 18yrs., clinically diagnosed as having oral lichen planus with burning sensation in the mouth and having oral lesions of lichen planus and willingness of the patients to voluntarily participate in the study. Patients who were asymptomatic, pregnant or lactating or having systemic conditions contraindicated for zinc supplementation or steroid therapy, hypersensitivity to zinc, or under therapy with steroids, immunosuppressants were excluded from the study.

Baseline demographic details and complete clinical examination findings were recorded for every participant, severity of burning sensation was assessed using a 10-cm Visual Analogue Scale (VAS), where 0 represented no pain and 10 represented the worst imaginable pain. Clinical lesion severity was evaluated using the Thongprasom scoring system. Clinical assessments were performed at baseline, day 7, day 14, and day 30 to evaluate treatment response. The primary outcome measures were reduction in burning sensation assessed using the visual analog scale and reduction in the severity of the lesion assessed using the Thongprasom scoring system. Data was entered into Microsoft Excel and analysed using Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM Corp., Armonk, NY, USA).

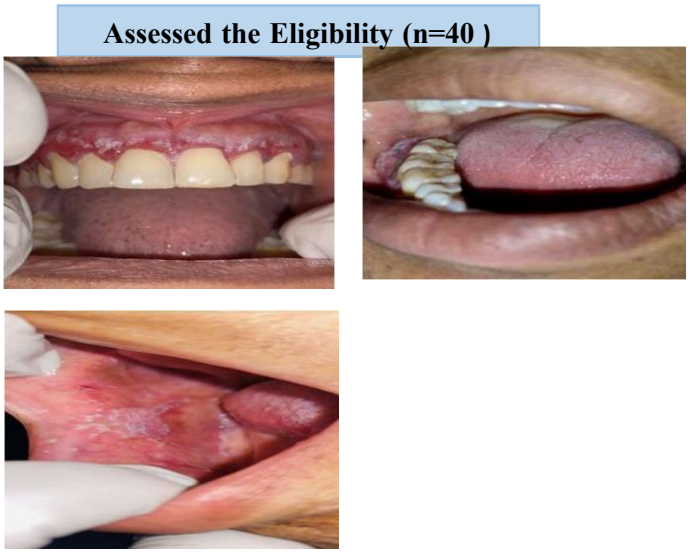
Descriptive statistics were expressed as mean ± standard deviation and frequency with percentage. Intergroup comparisons of continuous variables were performed using the independent t-test, whereas categorical variables were analysed using the chi-square test. Intragroup comparisons across follow-up visits were performed using the Friedman test, followed by Dunn's post hoc test where appropriate. p-value <0.05 was considered statistically significant.

Results

Participant characteristics: A total of 40 patients with oral lichen planus willing to participate were enrolled and randomly allocated into two groups (n=20 each). All participants completed the follow-up period and were included in the final analysis.

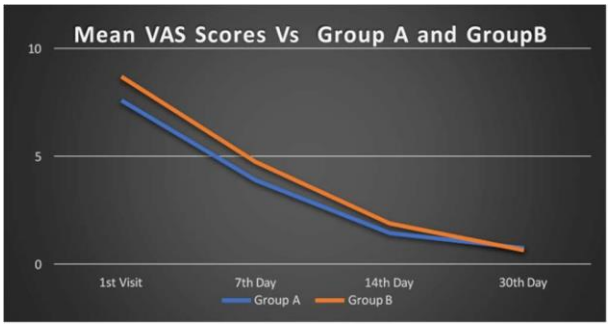
Baseline clinical presentation of oral lichen planus lesions

Figure 1: CONSORT flow diagram



Burning sensation assessment

In Group A, treated with topical 0.1% triamcinolone acetonide, the mean VAS score decreased from **7.60 ± 2.01** at baseline to **3.90 ± 1.25**, **1.45 ± 0.83**, and **0.75 ± 0.64** on days 7, 14, and 30, respectively. The reduction in burning sensation over the study period was statistically significant (**p = 0.001**).



Similarly, Group B, receiving oral zinc acetate as an adjunct to topical triamcinolone acetonide, showed a reduction in mean VAS scores from **8.70 ± 1.95** at baseline to **4.75 ± 2.12**, **1.90 ± 1.02**, and **0.65 ± 0.81** on days 7, 14, and 30, respectively (**p = 0.001**).

Mean Visual Analogue Scale (VAS) scores during follow-up

Intergroup comparison revealed no statistically significant differences in VAS scores between the groups at baseline (**p = 0.087**), day 7 (**p = 0.133**), day 14 (**p = 0.134**), or day 30 (**p = 0.668**).

Follow-up visit	Group A (Triamcinolone Acetonide) Mean ± SD	Group B (Zinc Acetate + Triamcinolone Acetonide) Mean ± SD	*P* value
Baseline	7.60 ± 2.010	8.70 ± 1.949	0.087
Day 7	3.90 ± 1.252	4.75 ± 2.124	0.133
Day 14	1.45 ± 0.826	1.90 ± 1.021	0.134

Follow-up visit	Group A (Triamcinolone Acetonide) Mean ± SD	Group B (Zinc Acetate + Triamcinolone Acetonide) Mean ± SD	*P* value
Day 30	0.75 ± 0.639	0.65 ± 0.813	0.668

Table 1. Mean Visual Analog Scale (VAS) scores during follow-up

Clinical evaluation using the Thongprasom scoring system demonstrated progressive improvement in both groups. At baseline, all participants exhibited white striae with associated atrophic areas. By day 30, complete clinical resolution was observed in 75% of patients in Group A and 80% of patients in Group B**.**

Comparison of Thongprasom score between Group A & Group B

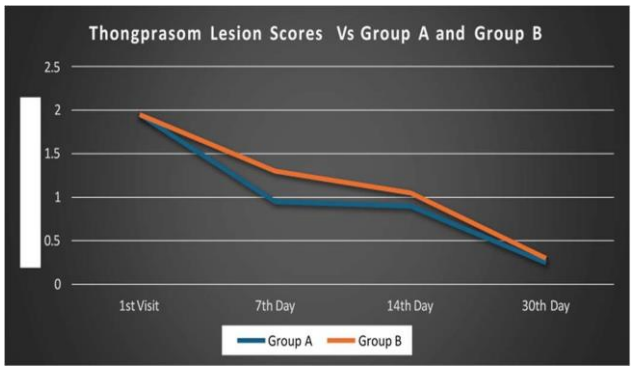


Table 2: Comparison of Thongprasom scores during follow-up

Follow-up visit	Group A (Triamcinolone Acetonide) n (%)	Group B (Zinc Acetate + Triamcinolone Acetonide) n (%)	*P* value
Baseline	White striae with atrophic area: 20 (100%)	White striae with atrophic area: 20 (100%)	1.000
Day 7	No lesion: 1 (5%) Mild white striae, no erythema: 19 (95%)	Mild white striae, no erythema: 14 (70%) White striae with atrophic area: 6 (30%)	**0.020***
Day 14	No lesion: 2 (10%) Mild white striae, no erythema: 18 (90%)	No lesion: 1 (5%) Mild white striae, no erythema: 19 (95%) White striae with atrophic area: 1 (5%)	0.487
Day 30	No lesion: 15 (75%) Mild white striae, no erythema: 5 (25%)	No lesion: 16 (80%) Mild white striae, no erythema: 2 (10%) White striae with atrophic area: 2 (10%)	0.349

A significant reduction in lesion severity was observed within both groups during follow-up. Intergroup compare son showed a statistically significant difference on day 7 (**p = 0.020**); however, no significant differences were observed at baseline, day 14, or day 30.

Oral Lichen Planus lesions before and after treatment

Overall, both treatment approaches resulted in significant

improvement in symptomatic and clinical parameters. The zinc acetate adjunctive therapy showed a higher proportion of complete lesion resolution, although the difference between groups was not statistically significant at the final evaluation.

Discussion

Oral lichen planus (OLP) is a chronic T-cell-mediated inflammatory disorder characterized by periods of remission and exacerbation. Although topical corticosteroids remain the cornerstone of therapy, recurrence and incomplete lesion resolution have encouraged the exploration of adjunctive agents with antioxidant and immunomodulatory properties. The present randomized clinical trial evaluated the efficacy of oral zinc acetate as an adjunct to topical triamcinolone acetonide in patients with symptomatic OLP. Both groups demonstrated significant improvement in burning sensation

and lesion severity during the one-month evaluation period, with the zinc acetate combination group showing a slightly better early clinical response.

The significant reduction in burning sensation observed in both groups supports the established effectiveness of topical triamcinolone acetonide in symptomatic OLP management. Corticosteroids exert their therapeutic action by suppressing T-cell-mediated immune activity, reducing inflammatory cytokine production, and decreasing epithelial inflammation, thereby promoting symptom relief and mucosal healing. Similar outcomes have been reported by Shreya Reddy Chelluri and Raj Kumar Badam et al. (2024), [37] Cheshta Walia et al. (2022), [38] Raj Srivastava et al. (2021), [39] A.R. Singh et al. (2017), [40] and Ronald Laeijendecker et al. (2006), [44] who demonstrated significant improvement in burning sensation following topical triamcinolone therapy. The findings of the present study are therefore consistent with previous evidence supporting corticosteroids as the first-line treatment for symptomatic OLP.

Patients receiving adjunctive zinc acetate showed marked clinical improvement, with greater early symptom reduction and a higher percentage of complete lesion resolution (80%) compared with the triamcinolone-only group (75%). Although the difference between groups was not statistically significant at one month, the improved early response in the combination group suggests that zinc may enhance the therapeutic effect of corticosteroids during the initial stages of treatment. Similar findings were reported by Akhilanand Chaurasia et al. (2018), [32] who observed clinical improvement following zinc supplementation in OLP patients. Tayyaba Fatima et al. (2016) [33] highlighted the antioxidant, anti-inflammatory, and immunomodulatory properties of zinc, while Magdalena Jarosz et al. (2017) [34] emphasized its role in epithelial regeneration and regulation of inflammatory responses.

The potential role of zinc in OLP management is further supported by studies demonstrating altered zinc status among affected patients. Neda Gholizadeh et al. (2014) [35] and Rezazadeh and Sokhakian (2018) [31] reported reduced serum zinc levels in patients with OLP, particularly in erosive forms, suggesting that zinc deficiency may contribute to increased disease severity and impaired mucosal healing. Zinc plays an important role in antioxidant defence, epithelial repair, immune modulation, and regulation of inflammatory pathways. Therefore, restoration of zinc levels may improve tissue healing and enhance the response to conventional corticosteroid therapy. The favourable clinical outcomes observed in the present study support this proposed mechanism.

Several recent clinical studies have further evaluated zinc as an adjunctive therapy in OLP. Farahat et al. (2024), [45] Bahramian et al. (2023), [6] Suvarna et al. (2020), [46] and Chaitanya et al. (2019) [47] reported improvements in pain intensity, lesion severity, and overall clinical response following zinc supplementation either alone or in combination with corticosteroids. The findings of the present study are in agreement with these reports, indicating that zinc acetate may have potential benefits as an adjunctive therapeutic agent in symptomatic OLP.

However, unlike Farahat et al., [45] who reported statistically significant superiority of adjunctive zinc therapy, the present study did not demonstrate a significant intergroup difference after one month. This variation may be attributed to differences in sample size, follow-up duration, zinc dosage and formulation, and clinical assessment methods. In the present study, clinical evaluation was performed after one month despite treatment continuation for two months, which may have limited the ability to identify significant differences between groups. Additionally, the relatively small sample size may have reduced the statistical power to detect subtle differences, despite the observed favourable trend with zinc supplementation.

The present study employed a randomized clinical trial design with standardized treatment protocols and evaluated both subjective and objective clinical outcomes using validated assessment tools, including the Visual Analogue Scale (VAS) and Thongprasom scoring system. These standardized measures improved the reliability and reproducibility of the findings. Furthermore, complete follow-up of all participants minimized the possibility of attrition bias.

The study sample size was limited due to time constraints and evaluated outcomes over only one month, although treatment was continued for two months. Biochemical parameters such as serum zinc levels, inflammatory cytokines, and oxidative stress markers were not assessed due to lack of suitable facilities, limiting the ability to correlate clinical improvement with underlying biological changes.

From a clinical perspective, the findings suggest that oral zinc acetate may be considered a safe, affordable, and easily available adjunct to topical corticosteroid therapy in patients with symptomatic OLP. The additional benefit observed with zinc was modest and clinically pertinent but not of statistical significance., The reduction in severity of symptoms and improved lesion resolution are important considerations, which obviously contribute to better patient comfort, treatment adherence, and quality of life.

Future multicentric randomized controlled trials with larger sample sizes and longer follow-up periods are required to establish the long-term therapeutic role of zinc acetate in OLP. Further investigations incorporating serum zinc estimation, oxidative stress markers, inflammatory mediators, and recurrence assessment may provide better understanding of the biological mechanisms and clinical effectiveness of zinc supplementation in oral lichen planus

Conclusion

Within the limitations of the present randomized clinical trial, both topical 0.1% triamcinolone acetonide alone and its combination with oral zinc acetate were effective in reducing burning sensation and lesion severity in patients with symptomatic oral lichen planus. Significant clinical improvement was observed in both treatment groups over the follow-up period.

The adjunctive zinc acetate group demonstrated earlier clinical improvement and a greater reduction in lesion severity, the differences between the two treatment groups were not statistically significant at the one-month evaluation. These findings suggest that oral zinc acetate may serve as a beneficial adjunct to conventional topical corticosteroid therapy by enhancing the clinical response, possibly through its antioxidant, anti-inflammatory, and immunomodulatory properties**.**

Considering the chronic and recurrent nature of oral lichen planus, adjunctive zinc supplementation is a safe adjunctive therapeutic option. However, larger multicentric randomized controlled trials with longer follow-up periods, histopathological grading, serum zinc level assessment, and evaluation of inflammatory biomarkers are required to establish its long-term efficacy and determine standardized treatment protocols.

Declarations

Ethics approval and consent to participate

This study received ethical approval from the Ethics Committee of Narayana Dental College and Hospital, Nellore, Andhra Pradesh, India, under the protocol number IEC/NDCH/2024/FEB-APR/P-46. Written informed consent was obtained from all participants before enrolment in the study. Consent for publication was obtained prior to their recruitment.

Competing interests The authors declare that they have no competing interests.

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